

Rejections Under 35 U.S.C. 112

Pages 2 through 12 of the Office Action are essentially a verbatim repeat of the prior Office Action of July 14, 2005. Claims 5 and 8 are again rejected 3 times under the first paragraph of 35 U.S.C. 112, as failing to possess enablement. The 3 rejections center upon the recitation of "tumor growth", "auto immune disorders" and "memory disturbances." At pages 2 through 12 of the Office Action, an analysis of factors set forth in *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988), is set forth. This analysis has been thoroughly responded to in Applicants' Reply of October 14, 2005, and the present record is not burdened by reiterating this discussion herein, although the discussion is incorporated by reference in the present response. In summary, with respect to all three rejections, Applicants' specification provides objective enablement, no reasons or evidence sufficient to doubt the assertion of utility in the specification has been provided, Applicants' claims are method claims which *per se* do not include inoperative embodiments, and, even if inoperative embodiments *were* contained within the scope of the present claims, it would not require undue experimentation in order to determine whether a given embodiment was operable and, thus, within the scope of the method claims.

The only rebuttal to Applicants' discussion in the prior reply is that found at page 13 of the Office Action, where it is alleged that Carter provides evidence rebutting Applicants' objective enablement. Applicants strenuously disagree. The cited pages of the Carter text book disclose various drug-tumor "interactions". They appear to suggest that some drugs do not "interact" with tumors located in the various areas listed, while others do. There is no explanation of this "interaction" and whether its significance translates to therapeutic modalities. There is no indication of the methodology used to determine the "interaction", and it is far from evident from Carter that even the lack of interaction translates to a lack of therapeutic utility. It is thus respectfully submitted that Carter fails to constitute the sort of "evidence" required by Marzocchi, *supra*, necessary to rebut a case of prima facie enablement.

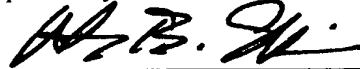
Moreover, as noted above, method claims are *per se* functional, see *In re Dinh-Nguyen*, 492 F.2d 856, 181 USPQ 46 (CCPA 1974). Thus, the only analysis needed is whether it would involve undue experimentation to determine whether a given compound is effective in the stated utility. As discussed at length in the prior response, undue experimentation is *not* required for

such a determination. Thus, it is again respectfully submitted that the rejections under 35 U.S.C. 112 should be withdrawn.

The claims of the application are again submitted to be in condition for allowance. However, if the Examiner has any comments or questions, he or she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Harry B. Shubin, Reg. No. 32,004
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: MERCK-2412-D01

Date: April 10, 2006

HBS:pdr

K:\Merck\2000 - 2999\2412\D01\Reply After Final Apr 06.doc